K123707
p. 1 of 2

FEB 2 8 2013

510(k) Summary

Submitted By:

David Lehr
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404

Device:

Trade Name: Alight™ 16 Superselective Microwire Guides
Proposed Classification: Wire, Guide, Catheter
DQX (21 CFR §870.1330)

Indications for Use:

Alight™ 16 Superselective Microwire Guides are intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Predicate Device:

Cook Incorporated's Alight™ 16 Superselective Microwire Guide is identical in terms of intended use and similar in terms of principles of operation, materials of construction, and technological characteristics to the predicate device. The device, subject of this submission, is substantially equivalent to the Roadrunner UniGlide Hydrophilic Wire Guide, manufactured by Cook Incorporated, which is cleared under 510(k) number K110009 (February 2, 2011).

Comparison to Predicate Device:

It has been demonstrated that the Alight™ 16 Superselective Microwire Guide is comparable to its predicate device in terms of design, intended use, materials, fundamental technology, and principle of operation.

Device Description:

Alight™ 16 Superselective Microwire Guides are 0.016 inches (0.41 mm) in diameter and are available in a variety of lengths and configurations. The core mandril of the Alight Superselective Microwire Guides is made of nitinol with a polymer coating and spans the entire length of the device to help facilitate flexibility and torqueability. The distal length of the device is covered with a hydrophilic coating.

Test Data:

The Alight™ 16 Superselective Microwire Guide was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Torque Response – Testing shows that all test articles were successfully subjected to rotational response testing. The predetermined acceptance criteria were met.

2. Hydrated Lubricity – Testing shows that the peak force of all test articles was less than the predetermined acceptance criteria.

3. Flexing Evaluation – No flaking was witnessed after testing. The predetermined acceptance criteria were met.

4. Fracture Evaluation – Testing shows that all test articles underwent bending testing without showing signs of fracture. The predetermined acceptance criteria were met.

5. Torque Strength Evaluation – Testing verifies that the device is sufficiently strong to withstand normal rotational loading for intended use. The predetermined acceptance criteria were met.

6. Tensile Evaluation – Testing verifies that the wire guide is sufficiently strong to withstand normal tensile loading for intended use in accordance with ISO 11070:2009. The predetermined acceptance criteria were met.

7. Tip Flexibility Evaluation – Testing was completed for characterization purposes only and therefore did not have a set acceptance criterion. The testing showed that the wire guide is sufficiently strong to withstand normal tensile loading for its intended use.

8. Biocompatibility – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogen, hemocompatibility, complement activation, partial thromboplastin time, and thromboresistance) shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and effective as the predicate device and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Cook Incorporated
c/o Mr. David Lehr, Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K123707
Trade Name: Alight™ 16 Superselective Microwire Guides
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II
Product Code: DQX
Dated: January 31, 2013
Received: February 4, 2013

Dear Mr. Lehr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Alight™ 16 Superselective Microwire Guides

Indications for Use:

Alight™ 16 Superselective Microwire Guides are intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR Over–the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner